

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Yelena Nabutovsky

Application No.: 10/687,846

Filed: October 17, 2003

For: Multifocal PVC Detection for  
Prevention of Arrhythmias

Examiner: Flory, Christopher A.

Art Unit: 3762

Confirmation No.: 9561

Docket No.: A03P3002-US1

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Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**ARGUMENTS TO ACCOMPANY THE PRE-APPEAL**  
**BRIEF REQUEST FOR REVIEW**

Dear Sir:

Applicant hereby submits the following Arguments as an attachment to the Pre-Appeal Brief Request for Review (Form PTO/SB/33). A Notice of Appeal is filed concurrently herewith.

**Summary Of Request**

Applicant respectfully submits that the outstanding rejections of the claims pending in the above identified application are improper and without legal or factual basis. Applicant further submits that the outstanding rejections can be readily reviewed and summarily resolved in light of the present record. Accordingly, Applicant requests review of the outstanding rejections pursuant to a pre-appeal conference.

In the Office action dated October 6, 2006, which was made final, the Examiner rejected claims 1-28 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 6,370,431 to Stoop et al. (hereinafter Stoop et al). Applicant's claimed invention, as recited in independent claims 1, 13, 17, 23 and 27, is

directed toward a method and corresponding apparatus for detecting and preventing ventricular arrhythmias based upon the difference between the morphologies of at least two premature ventricular contractions (hereinafter PVCs).

Stoop et al. do not disclose or suggest a method or device that detects and or prevents arrhythmias based upon the difference between the morphologies of at least two PVCs. The Examiner's continued use of Stoop et al. as an allegedly anticipatory reference is therefore improper. Accordingly, without more evidence of unpatentability, Applicant is entitled to grant of a patent and therefore respectfully requests that presently pending claims 1-28 be promptly allowed.

### **Argument**

The Examiner's October 10, 2006 Office action is the second Office action Applicant has received to date in response to their application for patent. With respect to Applicant's pending claims 1-28 the October 10, 2006 Office action maintains the Examiner's previous rejections in the April 10, 2006 Office action.

It is well settled that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference and that the identical invention must be shown in as complete detail as contained in the claim. (see MPEP §2131), *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed Cir. 1987).

Further, to serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with extrinsic evidence that makes clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill in the art. *Continental Can Co.*

USA vs. Monsanto Co. 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

The Examiner admits on page 2 of the Office Action dated October 10, 2006 that Stoop et al. do not disclose or suggest a method or system that detects and or prevents arrhythmias based upon the difference between the morphologies of at least two PVCs as recited in Applicant's claimed invention. The Examiner argues instead that Stoop et al. consider T-wave morphology in performing calculations to determine whether to deliver preventive therapy thereby anticipating Applicant's claimed invention.

More specifically, the Examiner asserts that Stoop et al. disclose using a difference in morphologies to determine whether to deliver preventive therapy since the time derivative curve of T-wave amplitude morphology as taught by Stoop et al. is nonetheless a measure of signal morphology. The Examiner further alleges that although a T-wave follows the first contraction it also precedes any subsequent PVCs, and in this way influences and is related to a PVC so that Stoop et al. anticipate the claimed invention. (page 2 of the Office Action dated October 10). Applicant respectfully disagrees.

Applicant submits that the Examiner provides no teaching that analyzing the QT interval, including the T-wave morphology, as taught by Stoop et al. is in any way identical to determining the difference between the morphology of two PVCs and comparing that difference to a threshold as would be required to anticipate Applicant's claimed invention. Further, the Examiner provides no teaching which indicates that the T-wave morphology (i.e. the morphology of the repolarization of the ventricle after a ventricular contraction), in any way influences the morphology of a subsequent PVC.

Applicant submits that unsupported allegations by the Examiner are not sufficient to sustain a rejection for anticipation. Moreover, Stoop et al. do not disclose or in any way suggest determining the difference between the morphologies of at least two PVCs and comparing the difference in morphologies to a threshold.

Rather, Stoop et al. disclose a pacemaker system and method for analyzing patient QT information on an ongoing basis, and for determining the occurrence of statistically significant changes in a plurality of QT parameters, thereby providing an accurate determination of when torsades de pointes (TdP) or other ventricular tachycardia is indicated. For example, Stoop et al. compare the current QT interval with a compiled mean value of the QT interval for an appropriate rate, and determine whether the QT interval has increased by more than twice the standard deviation of the mean. In other embodiments Stoop et al. perform similar calculations for QT dispersion and the time derivative of QT changes in T-wave amplitude and morphology. (Stoop et al., col. 2, lines 32-42).

Thus, in some embodiments Stoop et al. compare the morphology of a current T-wave to a compiled mean value of the T-wave. However, Stoop et al. do not disclose or suggest determining the morphology of two PVCs or determining whether to deliver preventive therapy based on a comparison of the difference between the morphologies of the two PVCs and a threshold as recited in Applicant's claimed invention. Further, the Examiner provides no indication as to how comparing the morphology of a current T-wave to a stored mean value is equivalent to determining the difference in the morphology of two PVCs and comparing that difference to a threshold as recited in Applicant's claimed invention.

Stoop et al. further disclose that in some embodiments the pacemaker of Stoop et al. determines whether a ventricular extra systole (VES) has occurred, and if so, what has been the recent rate of occurrence of VESs. This data is used to calculate whether pacing at an intervention rate above the patient's natural rate is indicated, and if so how to adjust the intervention rate. (Stoop et al., col. 2, lines 42-47). In these embodiments Stoop et al. analyze the rate of occurrence of PVCs not the difference between the morphologies of at least two PVCs.

Applicant submits that comparing the morphology of a current T-wave to a compiled mean value of the T-wave is not sufficient to anticipate a method and device that determines the difference in the morphology of two PVCs and compares that difference to a morphology threshold to detect a need for preventive therapy as recited in Applicant's claimed invention. Applicant further submits that a system that analyzes the rate of occurrence of PVCs when determining when to deliver therapy is not relevant to the presently claimed invention. Applicants therefore submit that independent claims 1, 13, 17, 23 and 27 and all claims which depend therefrom, are patentable over the cited art.

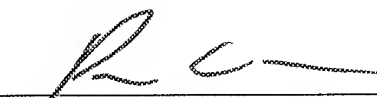
### Conclusion

Applicant submits that Stoop et al. does not therefore disclose each and every element as set forth in Applicant's claimed invention and does not therefore anticipate Applicant's claimed invention. Applicant therefore submits that the Examiner's continued reliance on Stoop et al. to support an anticipation rejection of the currently pending claims is improper. Applicants believe that the present application is in condition for allowance. Prompt and favorable consideration of Applicants' Pre-Appeal Brief Request for Review is respectfully requested.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 22-0265.

Respectfully submitted,

Dated: 1-8-07

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PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) <b>A03P3002-US1</b>	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u><b>E-FILED 01-08-07</b></u> Signature _____  Typed or printed name <u><b>ESTHER CAMPBELL</b></u>	Application Number <b>10/687,846</b>		Filed <b>OCT. 17, 2003</b>
	First Named Inventor <b>NABUTOVSKY</b>		
	Art Unit <b>3762</b>	Examiner <b>FLORY</b>	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/98)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u><b>47,822</b></u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p> <p><input checked="" type="checkbox"/> *Total of <u><b>1</b></u> forms are submitted.</p>			
<p>This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p>If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.</p>			